PATENT
Attorney Docket No. **STRATA-06949**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer *et al.*
Serial No.: 10/087,346 Group No.: 1632
Filed: 03/01/02 Examiner: Chen
Entitled: **Skin Substitutes With Improved Barrier Function**

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: October 15, 2003 By: Mary Ellen Waite
Mary Ellen Waite

Sir or Madam:

Enclosed please find a Supplemental Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

Applicants believe no fee is required. If the Commissioner deems otherwise, the Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. **08-1290**. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: October 15, 2003

J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
608/218-6900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer *et al.*
Serial No.: 10/087,346 Group No.: 1632
Filed: 03/01/02 Examiner: Chen
Entitled: **Skin Substitutes With Improved Barrier Function**

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **October 15, 2003**.

By: Mary Ellen Waite
Mary Ellen Waite

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- Berger *et al.*, Secreted placental Alkaline Phosphatase: A Powerful New Quantitative Indicator Of Gene Expression In Eukaryptic Cells, *Gene* 66:1-10 (1988)
- Gibbs *et al.*, Culture Of Reconstructed Epidermis In A Defined Medium at 33°C Shows A Delayed Epidermal Maturation, Prlonged Lifespan And

Improved Stratum Corneum, Arch Dermatol Res. 1997 Sep;289(10):585-95. Erratum in: Arch Dermatol Res 1998 Jan-Feb;290(1-2):28.

- Andraedis *et al.,* Keratinocyte growth factor induces hyperprofileration and delays differtiation in a skin equivalent model system, FASEB 15:898-906 (2001)
- Auger *et al.,* Multistep Production Of Bioengineered Skin Substitutes: SEquential Modulation Of Culture Conditions, In Vitro Cell Dev. Biol.-Animal 36:96-103 (2000)
- Chilcott *et al.,* Transepidermal Water Loss Does Not Correlate With Skin Barrier Function *In Vivo,* J. Investigative Dermatology 118:871-875 (2002)
- Goretsky *et al.,* Surface electrical capacitance as an index of epidermal barrier properties of composite skin substitutes and skin autografts, Wound Repair and Regeneration 3:419-425 (1995)
- Boyce *et al.,* Surface Electrical Capacitance as a Noninvasive Index of Epidermal Barrier in Cultured Skin Substitutes in Athymic Mice, Soc. for Investigative Dermatology, 82-87 (1996)
- Vicanova *et al.,* Incorporation of linoleic acid by cultured human keratinocytes,
- Swartzendruber *et al.,* Molecular Models of the Intercellular Lipid Lamellae in Mammalian Stratum Corneum, Soc. for Investigative Dermatology,92:251257 (1989)
- Ponec *et al.,* Lipid and ultrastructural scharacterization of reconstructed skin models, Int.l J. of Pharmaceutics, 203:211-225 (2000)
- Gibbs *et al.,* Temperature-sensitive regulation of epidermal morphogenesis and the expression of cornified envelope precursors by EGF and TGFα, Cell Tissue Res., 292:107-114 (1998)
- Uchida *et al.,* Vitamin C Stimulates Sphingolipid Production and Markers of Barrier Formation in Submerged Human Keratinocyte Cultures, Soc. for Investigative Dermatology, 117:1307-1313 (2001)
- Boyce *et al.,* Vitamin C Reggulates Keratinocyte Viability, Epidermal Barrier, and Basement Membrane *In Vitro*, and Reduces Wound Concentration After

Grafting of Cultured Skin Substitutes, Soc. for Investigative Dermatology, 118:565-572 (2002)

- Supp *et al.,* Incubation of cultured skin substitutes in reduced humidity promotes cornification in vitro and stable engraftment in athymic mice, Wound Repair and Regeneration, 7:226-237 (1999)
- Boyce *et al.,* Lipid Supplemented Medium Induces Lamellar Bodies and Precursors of Barrier Lipids in Cultured Analogues of Human Skin, Soc. for Investigative Dermatology, 101:180-184 (1993)
- Vicanova *et al.,* Normalization of Epidermal Calcium Distribution Profile in Reconstructed Human Epidermis Is Related to Improvement of Terminal Differentiation and Straum Corneum Barrier Formation, Soc. for Investigative Dermatology, 111:97-106 (1998)

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: October 15, 2003

J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 305
San Francisco, California 94105
608/218-6900

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: STRATA-06949	Serial No.: 10/087,346
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicant: Allen Comer *et al.*	
(37 CFR § 1.98(b))		Filing Date: 03/01/02	Group Art Unit:

		OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)
	1	Berger *et al.*, Secreted placental Alkaline Phosphatase: A Powerful New Quantitative Indicator Of Gene Expression In Eukaryptic Cells, *Gene* 66:1-10 (1988)
	2	Gibbs *et al.*, Culture Of Reconstructed Epidermis In A Defined Medium at 33°C Shows A Delayed Epidermal Maturation, Prlonged Lifespan And Improved Stratum Corneum, Arch Dermatol Res. 1997 Sep;289(10):585-95. Erratum in: Arch Dermatol Res 1998 Jan-Feb;290(1-2):28
	3.	Andraedis *et al.*, Keratinocyte growth factor induces hyperprofileration and delays differtiation in a skin equivalent model system, FASEB 15:898-906 (2001)
	4.	Auger *et al.*, Multistep Production Of Bioengineered Skin Substitutes: SEquential Modulation Of Culture Conditions, In Vitro Cell Dev. Biol.-Animal 36:96-103 (2000)
	5.	Chilcott *et al.*, Transepidermal Water Loss Does Not Correlate With Skin Barrier Function *In Vivo*, J. Investigative Dermatology 118:871-875 (2002)
	6	Goretsky *et al.*, Surface electrical capacitance as an index of epidermal barrier properties of composite skin substitutes and skin autografts, Wound Repair and Regeneration 3:419-425 (1995)
	7	Boyce *et al.*, Surface Electrical Capacitance as a Noninvasive Index of Epidermal Barrier in Cultured Skin Substitutes in Athymic Mice, Soc. for Investigative Dermatology, 82-87 (1996)
	8	Vicanova *et al.*, Incorporation of linoleic acid by cultured human keratinocytes, Arch Dermatol Res. 291:405-412 (1999)
	9	Swartzendruber *et al.*, Molecular Models of the Intercellular Lipid Lamellae in Mammalian Stratum Corneum, Soc. for Investigative Dermatology,92:251257 (1989)
	10	Ponec *et al.*, Lipid and ultrastructural scharacterization of reconstructed skin models, Int.l J. of Pharmaceutics, 203:211-225 (2000)
	11	Gibbs *et al.*, Temperature-sensitive regulation of epidermal morphogenesis and the expression of cornified envelope precursors by EGF and TGFα, Cell Tissue Res., 292:107-114 (1998)
	12	Uchida *et al.*, Vitamin C Stimulates Sphingolipid Production and Markers of Barrier Formation in Submerged Human Keratinocyte Cultures, Soc. for Investigative Dermatology, 117:1307-1313 (2001)
	13	Boyce *et al.*, Vitamin C Reggulates Keratinocyte Viability, Epidermal Barrier, and Basement Membrane *In Vitro*, and Reduces Wound Concentration After Grafting of Cultured Skin Substitutes, Soc. for Investigative Dermatology, 118:565-572 (2002)
	14	Supp *et al.*, Incubation of cultured skin substitutes in reduced humidity promotes cornification in vitro and stable engraftment in athymic mice, Wound Repair and Regeneration, 7:226-237 (1999)
	15	Boyce *et al.*, Lipid Supplemented Medium Induces Lamellar Bodies and Precursors of Barrier Lipids in Cultured Analogues of Human Skin, Soc. for Investigative Dermatology, 101:180-184 (1993)
	16	Vicanova *et al.*, Normalization of Epidermal Calcium Distribution Profile in Reconstructed Human Epidermis Is Related to Improvement of Terminal Differentiation and Straum Corneum Barrier Formation, Soc. for Investigative Dermatology, 111:97-106 (1998)

Examiner:	Date Considered:

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.